ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2012-0217; FRL-9922-38-OW]

RIN 2040-A537

Drinking Water Contaminant Candidate List 4– Draft

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is publishing for public review and comment a draft list of contaminants that are currently not subject to any proposed or promulgated national primary drinking water regulations. These contaminants are known or anticipated to occur in public water systems and may require regulation under the Safe Drinking Water Act (SDWA). This draft list is the fourth Contaminant Candidate List (CCL 4) published by the agency since the SDWA amendments of 1996. This Draft CCL 4 includes 100 chemicals or chemical groups and 12 microbial contaminants. The EPA seeks comment on the Draft CCL 4 and on improvements to the selection process for future CCLs for the agency to consider.

DATES: Comments must be received on or before [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OW-2012-0217, by one of the following methods:

- http://www.regulations.gov: Follow the on-line instructions for submitting comments.
- Mail: Water Docket, Environmental Protection Agency, Mail code: 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460.

- Hand Delivery: Water Docket, EPA Docket Center (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC 20004. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-HQ-OW-2012-0217. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at http://www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through http://www.regulations.gov or email. The http://www.regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through http:/www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional instructions on submitting comments, go to Section I.B of the **GENERAL INFORMATION** section of this document.

Docket: All documents in the docket are listed in the http://www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in http://www.regulations.gov or in hard copy at the Water Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC 20004. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the EPA Docket Center is (202) 566-2426.

FOR FURTHER INFORMATION CONTACT: For information on chemical contaminants contact Meredith Russell, Office of Ground Water and Drinking Water, Standards and Risk Management Division, at (202) 564-0814 or e-mail russell.meredith@epa.gov. For information on microbial contaminants contact Hannah Holsinger, Office of Ground Water and Drinking Water, Standards and Risk Management Division, at (202) 564-0403 or email holsinger.hannah@epa.gov. For general information contact the EPA Safe Drinking Water Hotline at (800) 426-4791 or e-mail: hotline-sdwa@epa.gov.

Abbreviations and Acronyms

ATSDR -- Agency for Toxic Substances and Disease Registry

CA -- California

CASRN -- Chemical Abstract Services Registry Number

CDC -- Centers for Disease Control and Prevention

CCL -- Contaminant Candidate List

CCL 1 -- EPA's First Contaminant Candidate List

CCL 2 -- EPA's Second Contaminant Candidate List

CCL 3 -- EPA's Third Contaminant Candidate List

CCL 4 -- EPA's Fourth Contaminant Candidate List

CFR -- Code of Federal Regulations

EPA -- United States Environmental Protection Agency

ESA -- Ethanesulfonic acid

FL -- Florida

FR -- Federal Register

HPC -- Heterotrophic Plate Count

IL -- Illinois

MCL -- Maximum Contaminant Level

MCLG – Maximum Contaminant Level Goal

MMWR -- Morbidity and Mortality Weekly Report

NC -- North Carolina

NCOD -- National Contaminant Occurrence Database

NDWAC -- National Drinking Water Advisory Council

NRC -- National Academy of Science's National Research Council

NPDWR -- National Primary Drinking Water Regulation

OH -- Ohio

PCCL 3 -- Preliminary Contaminant Candidate List 3

PCCL 4 -- Preliminary Contaminant Candidate List 4

PFOA -- Perfluorooctanoic Acid

PFOS -- Perfluorooctane Sulfonic Acid

PWS -- Public Water System

SAB -- Science Advisory Board

SDWA -- Safe Drinking Water Act

SD -- South Dakota

STORET -- EPA's Storage and Retrieval database of water quality monitoring data collected by water resource management groups across the U.S.

TX -- Texas

UCM -- Unregulated Contaminant Monitoring

UCMR 1 -- First Unregulated Contaminant Monitoring Rule

UCMR 2 -- Second Unregulated Contaminant Monitoring Rule

USDA -- United States Department of Agriculture

USEPA -- United States Environmental Protection Agency

USGS -- United States Geological Survey

WHO -- World Health Organization

WI -- Wisconsin

SUPPLEMENTARY INFORMATION:

Table of Contents

I. General Information

A. Does this Action Impose Any Requirements on My Public Water System?

The Draft Contaminant Candidate List 4 (CCL 4) and the Final CCL 4, when published, will not impose any requirements on regulated entities.

B. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

- Explain your views as clearly as possible.
- Describe any assumptions that you used.
- Provide any technical information and/or data you used that support your views.
- Provide full references for any peer reviewed publication you used that support your views.
- Provide specific examples to illustrate your concerns.
- Offer alternatives.

Make sure to submit your comments by the comment period deadline. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and Federal Register citation related to your comments.

II. Purpose, Background and Summary of This Action

This section briefly summarizes the purpose of this action, the statutory requirements, previous activities related to the Contaminant Candidate List (CCL) and the approach used to develop the Draft CCL 4.

A. What is the Purpose of This Action?

The Safe Drinking Water Act (SDWA), as amended in 1996, requires EPA to publish a list every five years of currently unregulated contaminants that may pose risks for drinking water (referred to as the Contaminant Candidate List, or CCL). This list is subsequently used to make regulatory determinations on whether to regulate at least five contaminants from the CCL with national primary drinking water regulations (NPDWRs) (SDWA section 1412(b)(1)). The purpose of today's action is to present EPA's draft list of contaminants on the CCL 4 and the rationale for the selection process used to make the list. Today's action only addresses the CCL 4. Regulatory determinations for contaminants on the CCL are a separate agency action.

EPA requests comment on the Draft CCL 4 and suggestions for further improvements to the selection process for future CCLs for the agency to consider.

B. Statutory Requirements for CCL, Regulatory Determinations and Unregulated Contaminant Monitoring

1. Contaminant Candidate List

Section 1412(b)(1) of the SDWA, as amended in 1996, requires EPA to publish the CCL every five years. The SDWA specifies that the list must include contaminants that are not subject

to any proposed or promulgated NPDWRs, are known or anticipated to occur in public water systems (PWSs), and may require regulation under the SDWA. The unregulated contaminants considered for listing shall include, but not be limited to, hazardous substances identified in section 101(14) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, and substances registered as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act. The SDWA directs the agency to consider the health effects and occurrence information for unregulated contaminants to identify those contaminants that present the greatest public health concern related to exposure from drinking water. The statute further directs the agency to take into consideration the effect of contaminants upon subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly and individuals with a history of serious illness or other subpopulations) that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population. EPA considers age-related subgroups as "lifestages" in reference to a distinguishable time frame in an individual's life characterized by unique and relatively stable behavioral and/or physiological characteristics that are associated with development and growth. Thus, childhood is viewed as a sequence of lifestages, from conception through fetal development, infancy and adolescence (see http://www2.epa.gov/children/early-life-stages).

2. Regulatory Determinations

Section 1412(b)(1)(B)(ii) of the SDWA, as amended in 1996, requires EPA at five year intervals, to make determinations of whether or not to regulate no fewer than five contaminants

from the CCL. The 1996 SDWA Amendments specify three criteria to determine whether a contaminant may require regulation:

- The contaminant may have an adverse effect on the health of persons;
- The contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and
- In the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

If EPA determines that these three statutory criteria are met and makes a final determination to regulate a contaminant, the agency has 24 months to publish a proposed Maximum Contaminant Level Goal[1] (MCLG) and NPDWR[2]. After the proposal, the agency has 18 months to publish and promulgate a final MCLG and NPDWR (SDWA section 1412(b)(1)(E))[3].

3. Unregulated Contaminant Monitoring

Section 1445 of the SDWA mandates that EPA promulgate regulations (known as the Unregulated Contaminant Monitoring Rule or UCMR) to establish criteria for a monitoring program for unregulated contaminants. The SDWA requires all large public water systems and a

[1] The MCLG is the "maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, and which allows an adequate margin of safety. Maximum contaminant level goals are non-enforceable health goals." (40 CFR 141.2; 42 U.S.C. 300g-1)

[2] An NPDWR is a legally enforceable standard that applies to public water systems. An NPDWR sets a legal limit (called a maximum contaminant level or MCL) or specifies a certain treatment technique for public water systems for a specific contaminant or group of contaminants. The MCL is the highest level of a contaminant that is allowed in drinking water and is set as close to the MCLG as feasible, using the best available treatment technology and taking cost into consideration.

[3] The statute authorizes a nine month extension of this promulgation date.

representative sample of smaller public water systems to monitor for unregulated contaminants. The statute requires EPA to issue a list every five years of not more than 30 unregulated contaminants to be monitored. The SDWA also specifies that EPA include the results of such monitoring, along with monitoring data for regulated contaminants and reliable information from other public and private sources, in a national drinking water occurrence database. EPA developed the National Contaminant Occurrence Database (NCOD) to contain the monitoring data from the UCMR program and other data as specified by the SDWA. The current UCMR (UCMR 3) requires monitoring for 30 contaminants (28 chemicals and two viruses) (77 FR 26071, May 2, 2012 (USEPA, 2012a)). Sampling is occurring during 2013-2015. Twenty-one of the contaminants being monitored under UCMR3 are included on the CCL 3 and 20 contaminants being monitored under UCMR3 are included on the Draft CCL 4.

C. Interrelationship of the CCL, Regulatory Determinations and Unregulated Contaminant Monitoring

The CCL is the first step in evaluating the subset of potential contaminants that may require future NPDWRs. The CCL serves as the initial screening of potential contaminants, and inclusion on the CCL does not mean that any particular contaminant will necessarily be regulated in the future. The UCMR provides a mechanism to obtain nationally representative occurrence data for contaminants. Most unregulated contaminants chosen by EPA for monitoring have been selected from the CCL. When selecting contaminants for monitoring under the UCMR, EPA considers the availability of health effects data and the need for national occurrence data for contaminants, as well as analytical method availability and cost, availability of analytical standards and laboratory capacity to support a nationwide monitoring program. The contaminant

occurrence data collected under the UCMR serves to better inform future CCLs and regulatory determinations. Contaminants on the CCL are evaluated to see which ones have sufficient information to allow the agency to make a regulatory determination. Those contaminants with sufficient information to make a regulatory determination are then evaluated based on the three statutory criteria in SDWA section 1412(b)(1), to determine whether a regulation is required (called a positive determination) or not required (called a negative determination). EPA must make regulatory determinations for at least five contaminants listed on the CCL every five years. For those contaminants without sufficient information to allow the agency to make a regulatory determination, EPA encourages research to provide the information needed to determine whether to regulate the contaminant. Today's action addresses only the CCL 4 and not the UCMR or regulatory determinations.

D. Summary of Previous CCLs and Regulatory Determinations

1. The First Contaminant Candidate List

The first CCL (CCL 1) was published on March 2, 1998 (63 FR 10274 (USEPA, 1998)). CCL 1 was developed based on recommendations by the National Drinking Water Advisory Council (NDWAC) and review by technical experts. It contained 50 chemicals and 10 microbial contaminants/groups. EPA consulted with the scientific community, including the Science Advisory Board, on a process for developing the first CCL.

2. The Regulatory Determinations for CCL 1 Contaminants

EPA published its final regulatory determinations for a subset of contaminants listed on CCL 1 on July 18, 2003 (68 FR 42898 (USEPA, 2003)). EPA identified nine contaminants from

the 60 contaminants listed on CCL 1 that had sufficient data and information available to make regulatory determinations. The nine contaminants were *Acanthamoeba*, aldrin, dieldrin, hexachlorobutadiene, manganese, metribuzin, naphthalene, sodium and sulfate. The agency determined that an NPDWR was not necessary for any of these nine contaminants at that time. The agency subsequently issued guidance on *Acanthamoeba* and Health Advisories for manganese, sodium and sulfate.

3. The Second Contaminant Candidate List

The agency published its Final CCL 2 on February 24, 2005 (70 FR 9071 (USEPA, 2005)). The agency carried forward the 51 remaining chemical and microbial contaminants from CCL 1 (that did not have regulatory determinations) to CCL 2.

4. The Regulatory Determinations for CCL 2 Contaminants

EPA published its final regulatory determinations for a subset of contaminants listed on CCL 2 on July 30, 2008 (73 FR 44251 (USEPA, 2008b)). EPA identified 11 contaminants from the 51 contaminants listed on CCL 2 that had sufficient data and information available to make regulatory determinations. The 11 contaminants were boron, the dacthal mono- and di-acid degradates; 1,1-dichloro-2,2-bis (p-chlorophenyl) ethylene (DDE); 1,3-dichloropropene; 2,4-dinitrotoluene; 2,6-dinitrotoluene; s-ethyl propylthiocarbamate (EPTC); fonofos; terbacil; and 1,1,2,2-tetrachloroethane. The agency made a final determination that an NPDWR was not necessary for any of these 11 contaminants. New or updated Health Advisories were subsequently issued for boron, the dacthal degradates, 2,4- dinitrotoluene, 2,6- dinitrotoluene and 1,1,2,2- tetrachloroethane.

5. The Third Contaminant Candidate List

The agency published its Final CCL 3 on October 8, 2009 (74 FR 51850 (USEPA, 2009e)). The CCL 3 contained 104 chemicals or chemical groups and 12 microbial contaminants. In developing CCL 3, EPA improved and built upon the process that was used for CCL 1 and CCL 2. In 1998, the agency requested advice from the National Academy of Sciences' National Research Council (NRC) on how to improve the CCL process. The NRC recommended more reproducible process whereby a broadly defined "universe" of potential drinking water contaminants is identified, assessed and reduced to a preliminary CCL (PCCL) using simple screening criteria (NRC, 2001). All of the contaminants on the PCCL would then be evaluated in more detail to assess the likelihood that specific contaminants could occur in drinking water at levels that pose a public health concern. In 2002, the agency sought input from the NDWAC on how to implement the NRC's recommendations to improve the CCL process. NDWAC agreed that EPA should proceed with the NRC's recommendations and provided additional considerations and recommendations in a 2004 report (NDWAC, 2004).

Based on these consultations, public input and peer review, EPA developed a multi-step process to select contaminants for the CCL 3, which included the following key steps:

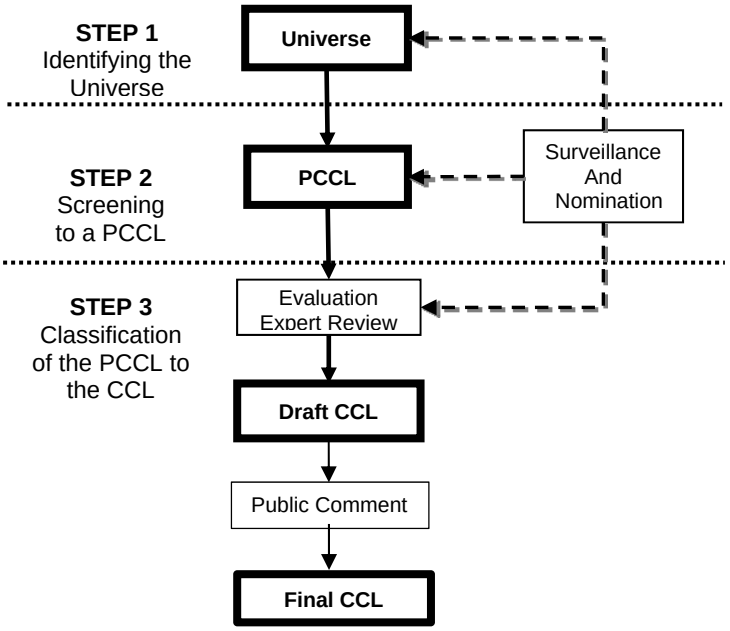
- Identification of a broad universe of potential drinking water contaminants (the CCL 3 Universe);
- Screening the CCL 3 Universe to a PCCL, using criteria based on the potential to occur in public water systems and the potential for public health concern;
- Evaluation of the PCCL contaminants based on a more detailed evaluation of occurrence and health effects data, using a scoring and classification system; and

- Incorporating public input and expert review in the CCL 3 process.

EPA also considered new information on contaminants identified by surveillance efforts, which included collaboration with internal EPA offices and other federal agencies and the review of scientific publications and data. The agency provided the public with the opportunity to nominate contaminants to be considered for the Draft CCL 3 and sought public comment on the Draft CCL 3 before the list was finalized.

Exhibit 1 illustrates the multi-step CCL 3 approach. This generalized process was applied to both chemical and microbial contaminants, though the specific execution of particular steps differs between them.

Exhibit 1. Schematic of CCL process



A complete description of the CCL 3 process can be found in the Draft and Final CCL 3 Federal Register documents (73 FR 9628, February 21, 2008 (USEPA, 2008a) and 74 FR 51850, October 8, 2009 (USEPA, 2009e)). Supporting documents that explain each stage of the CCL 3 process in further detail (i.e., identifying the CCL 3 Universe, screening to the PCCL, and the classification of the PCCL to the CCL) can be found at: http://water.epa.gov/scitech/drinkingwater/dws/ccl/ccl3_processflowdiagram.cfm and in the CCL 3 docket at www.regulations.gov (Docket ID: EPA-HQ-OW-2007-1189).

6. The Regulatory Determinations for CCL 3 Contaminants

On February 11, 2011, as a separate action, the agency issued a positive regulatory determination for perchlorate, a chemical listed in CCL 1, CCL 2 and CCL 3 (76 FR 7762; USEPA, 2011). Recently, EPA published preliminary regulatory determinations for five unregulated contaminants (79 FR 62716, October 20, 2014 (USEPA, 2014a)). The five contaminants include: 1,3-dinitrobenzene; dimethoate; strontium; terbufos; and terbufos sulfone. The agency is making preliminary determinations to regulate one contaminant (strontium) and to not regulate four contaminants (1,3-dinitrobenzene, dimethoate, terbufos, and terbufos sulfone). Therefore, the agency is removing perchlorate and these five contaminants from the Draft CCL 4, pending the result of the final regulatory determinations for CCL 3.

E. Summary of the Approach Used to Identify and Evaluate Candidates for CCL 4

EPA proposes an abbreviated three step evaluation and selection process for CCL 4: (1) carrying forward CCL 3 contaminants (except those with regulatory determinations), (2) seeking and evaluating nominations from the public for additional contaminants to consider, and (3)

evaluating any new data for those contaminants with previous negative regulatory determinations from CCL 1 or CCL 2 for potential inclusion on the CCL 4. The agency also seeks comment on how to further improve upon the process developed for CCL 3 as a tool for future CCLs.

1. Carry Forward of CCL 3 Contaminants

EPA carried forward all contaminants listed on CCL 3 to the Draft CCL 4 with the exception of perchlorate, for which the agency made a positive regulatory determination, and the five CCL 3 contaminants with preliminary regulatory determinations (listed in Section D.6 of this notice), pending their final determinations. This carry forward process is consistent with that previously used in CCL 2. The agency has taken this approach based on the following considerations: (1) In developing the CCL 3, the agency implemented a robust process recommended by the NRC and the NDWAC to screen and score the universe of potential contaminants, (2) EPA used the best available, peer-reviewed data and information to evaluate contaminants for CCL 3; and (3) Carrying forward CCL 3 contaminants allows the agency to focus resources on evaluating contaminants nominated by the public for CCL 4 and review new data for CCL 1 or CCL 2 contaminants with previous negative regulatory determinations.

2. Summary and Evaluation of CCL 4 Nominated Contaminants

a. CCL 4 Nominations Summary

EPA sought public nominations in a *Federal Register* document on May 8, 2012, for contaminants to be considered for possible inclusion in the CCL 4 (77 FR 27057 (USEPA, 2012b)). In the document, the agency also requested supporting information that has been made available since the development of the CCL 3, or existing information that was not considered

for CCL 3, which shows that the nominated contaminant may have an adverse effect on people and occurs or is likely to occur in public water systems.

EPA received nominations for 59 unique contaminants for the CCL 4, including 54 chemicals and five microbials. Eight contaminants were nominated by more than one organization or individual. Aldicarb, bisphenol A, carbaryl, chlorpyrifos, *Toxoplasma gondii*, and Microcystin-LR were each nominated by two separate organizations or individuals. Manganese and perfluorooctanoic acid (PFOA) were each nominated by three different organizations or individuals.

Nominations were received from 10 different organizations and/or individuals. The agency did not require nominators to provide their name or an affiliated organization. Two nominators remained anonymous while providing documentation and rationale for the contaminants. Two other individuals identified themselves but did not provide an organization affiliation. The identified organizations that nominated contaminants were:

- American Water Works Association,
- Natural Resources Defense Council,
- Massachusetts Department of Environmental Protection,
- Minnesota Department of Health,
- New Jersey Department of Environmental Protection, and
- U.S. Department of Agriculture (USDA).

EPA received three general types of nominations:

- Specific individual chemicals,

- Specific individual organisms, and
- Groups of contaminants (e.g., Heterotrophic Plate Count was considered as a group).

The American Water Works Association also provided a letter with recommendations for the CCL 4 process. The full text of this letter and all of the nomination submittals in their original form can be found at http://www.regulations.gov (docket ID: EPA-HQ-OW-2012-0217). Exhibit 2 contains the specific contaminants identified in public nominations. A more detailed summary of the nominations process is included in the support document "Summary of Nominations for the Fourth Contaminant Candidate List" (USEPA, 2015e).

Exhibit 2. Contaminants Nominated for Consideration on the Draft CCL 4:

Nominated Microbial Contaminants

Adenovirus
Heterotrophic Plate Count Bacteria (HPC)
Naegleria fowleri
Toxoplasma gondii
Vibrio cholerae

Nominated Chemical Contaminants

Common Name – Registry Name	**CASRN**
3-chloro-4-dichloromethyl-5-hydroxy-2(5H)-furanone	77439-76-0
alpha-Hexachlorocyclohexane	319-84-6
Aldicarb	116-06-3
Alkylphenol mono- to tri-oxylates	68555-24-8
Amoxicillin	26787-78-0
Azinphos-methyl	86-50-0

Common Name – Registry Name	CASRN
Bacitracin zinc	1405-89-6
Bentazone	25057-89-0
Benzyl butyl phthalate	85-68-7
Bisphenol A	80-05-7
Bromoxynil	1689-84-5
Carbaryl	63-25-2
Cesium 137	10045-97-3
Chlorothalonil	1897-45-6
Chlorpyrifos	2921-88-2
Dibutyl phthalate	84-74-2
Dicamba	1918-00-9
Dichlorvos	62-73-7
Dicofol	115-32-2
Dicyclohexyl phthalate	84-61-7
Diethyl phthalate	84-66-2
Di-isononyl phthalate	28553-12-0
Dimethyl phthalate	131-11-3
Di-n-octyl phthalate	117-84-0
Endosulfan	115-29-7
Fluometuron	2164-17-2
Linezolid	165800-03-3
Linuron	330-55-2
Malathion	121-75-5
Manganese	7439-96-5
Methicillin	61-32-5
Methyl parathion	298-00-0
Methyl tertiary butyl ether (MTBE)	1634-04-4
Microcystin-LR	101043-37-2

Common Name – Registry Name	CASRN
Nonylphenol	25154-52-3
Nonylphenol ethoxylate	9016-45-9
Octylphenol	27193-28-8
Octylphenol ethoxylate	9036-19-5
Oxacillin	66-79-5
Penicillin	(multiple CASRNs)
Perfluorooctanoic acid (PFOA)	335-67-1
Permethrin	52645-53-1
Phosmet	732-11-6
Progesterone	57-83-0
Radon	10043-92-2
Spiramycin	8025-81-8
Strontium 90	121831-99-0
Testosterone	58-22-0
Trichlorfon	52-68-6
Triclocarban	101-20-2
Triclosan	3380-34-5
Tylosin	1401-69-0
Vancomycin	1404-90-6
Virginiamycin	11006-76-1

b. Evaluation of Nominated Contaminants and Data Sources

The SDWA specifies that the CCL only include those contaminants without any proposed or promulgated NPDWRs. Two nominated contaminants are covered under the existing NPDWR for beta photon emitters (40 CFR §141.66 (d)(1)) (i.e., strontium 90 and cesium 137), hence, the agency will not consider them for CCL 4. Radon was also nominated, but is not eligible for CCL 4 since the agency developed and proposed a NPDWR (64 FR 59245, November 2, 1999

(USEPA, 1999). Aldicarb was nominated but is not eligible for CCL 4 since it has an existing NPDWR (40 CFR §141.61(c)); (Note, in response to an administrative petition, the agency issued an administrative stay of the effective date of the maximum contaminant levels for aldicarbs).

For the remaining 55 nominated contaminants, EPA reviewed the nominations and supporting information to determine if any new data were provided that had not been previously evaluated for CCL 3. Seven of the nominated contaminants were on CCL 3 and were carried forward to the Draft CCL 4, however the agency subsequently excluded those seven from the CCL 4 Universe. The agency also collected additional data for the nominated contaminants, when it was available, from both updated CCL 3 data sources and from new data sources that were not available at the time the agency finalized CCL 3. A complete list of references provided by nominators can be found in the support document "Summary of Nominations for the Fourth Contaminant Candidate List" (USEPA, 2015e). A more detailed description of the CCL data sources collected by EPA may be found in the support document "Data Sources for the Contaminant Candidate List 4" (USEPA, 2015c)). If new data were available, EPA screened and scored the nominated contaminants using the same process that was used in CCL 3.

Data sources for chemical and microbial contaminants

For nominated chemicals, occurrence data was collected from updated CCL 3 data sources including:

- 2006 production data collected in the Chemical Update System under the Inventory Update Rule,
- 2010 data from the Toxics Release Inventory,

- 2003-2009 data from the USDA Pesticide Data Program, and
- EPA's Storage and Retrieval (STORET) data as of January 2013.

Additional occurrence data for the nominated chemicals were collected from data sources that are new since the CCL 3 including:

- United States Geological Survey (USGS) studies that focused on contaminant occurrence in source waters for public water systems (Hopple et al., 2009, and Kingsbury et al., 2008) and water quality in public-supply wells (Toccalino et al., 2010);
- Individual State public water supply data provided to EPA during the second Six-Year Review of regulated contaminants (for the time period covering 1998-2005) from States including: CA, EPA Region 9 Tribes, FL, IL, NC, OH, SD, TX and WI;
- Data from The California State Water Resources Control Board's Groundwater Ambient Monitoring Assessment program; and
- New data from an EPA literature review of published studies on pharmaceuticals, personal care products and other contaminants.

In addition to health effects data provided by the nominators, EPA searched for health effects data for the nominated chemicals from data sources used in CCL 3 that may have been updated including:

- EPA's Integrated Risk Information System program,
- EPA's Office of Pesticide Programs,
- The Agency for Toxic Substances and Disease Registry (ATSDR),
- The California EPA (Office of Environmental Health Hazard Assessment),
- The Institute of Medicine,

- The National Toxicology Program, and
- The World Health Organization (WHO).

EPA also considered new or updated health effects information contained in the agency's Office of Superfund Remediation and Technology Innovation Provisional Peer Reviewed Toxicity Values.

For microbial contaminants, EPA evaluated waterborne disease outbreak data, and occurrence and health effects data, from data sources used in CCL 3, which have been updated (Murray et al., 2011; CDC, 2008; CDC, 2011). EPA also collected and evaluated information for microbial contaminants from data sources that are new since publication of the Final CCL 3.

A more detailed description of the data sources used to evaluate contaminants for CCL 4 can be found in the support document "Data Sources for the Contaminant Candidate List 4" (USEPA, 2015c) available at http://www.regulations.gov (Docket ID: EPA-HQ-OW-2012-0217).

c. Outcomes for the CCL 4 Nominated Contaminants

Forty-three of the nominated chemicals were included in the CCL 4 Universe. Forty of the nominated chemicals were previously included in the CCL 3 Universe and were carried forward to the CCL 4 Universe. In addition to these 40, EPA added three nominated chemicals (i.e., octylphenol ethoxylate, oxacillin, and virginiamycin) to the CCL 4 Universe based on health effects and/or occurrence data that is newly available since the Final CCL 3. EPA screened all of the nominated chemicals in the CCL 4 Universe according to the screening criteria developed for CCL 3 and based on that evaluation, the agency included 20 of the nominated chemicals on the PCCL 4. Eighteen of those 20 chemicals were also included in the

PCCL 3, and EPA added two new chemicals (manganese and nonylphenol) to the PCCL 4. The data used to screen the nominated chemicals from the CCL 4 Universe to the PCCL 4 can be found in the "Screening Document for the Draft PCCL 4 Nominated Contaminants" (USEPA, 2015d). EPA further evaluated the nominated chemicals on the PCCL 4 based on the classification process developed in CCL 3 and determined that manganese and nonylphenol should be added to the Draft CCL 4 based on new health and/or occurrence information (in addition to the chemicals carried forward from the CCL 3). The data that the agency used to further evaluate the nominated contaminants from the PCCL 4, and to select those that were included in the Draft CCL 4, can be found in the "Contaminant Information Sheets (CISs) for the Draft Fourth Preliminary Contaminant Candidate List (PCCL 4) Nominated Contaminants" (USEPA, 2015b).

Manganese is an element that naturally occurs in oxide forms and in combinations with other elements in many minerals. Manganese is an essential nutrient for humans and animals. Manganese ores are used in a variety of applications in the United States. Its principal use is in steel production to improve hardness, stiffness and strength (ATSDR, 2012). In 2003 and as part of the first (CCL 1) Regulatory Determination process, EPA made a negative regulatory determination for manganese based on the health and occurrence data available at that time. However, CCL 4 nominators cited more than 20 recent studies that indicate concern for neurological effects in children and infants exposed to excess manganese, which were not available at the time manganese was considered for the first Regulatory Determination or CCL 3. In addition, new monitoring studies from USGS and drinking water monitoring information from several States support an earlier survey (i.e., the National Inorganics and Radionuclides Survey),

which indicates manganese is known to occur in drinking water. EPA has determined that the new health effects information and additional occurrence data merit listing manganese in the Draft CCL 4.

Nonylphenol is used in the preparation of lubricating oil additives, resins, plasticizers and antioxidants for plastics and rubber. Additionally, 60 percent of nonylphenol is used in the production of nonylphenol ethoxylates, which are found in detergents and used in the treatment of textiles. Nonylphenol was previously considered for CCL 3. It was included in the CCL 3 Universe, but was not included in the PCCL 3 or CCL 3. Updated health and occurrence data are now available for nonylphenol, and these data were considered by the agency in evaluating nonylphenol for the Draft CCL 4. Nonylphenol and some of its degradation products have been found to have estrogenic activity in rats and mice (WHO, 2004), and additional occurrence data are available from a USGS National Reconnaissance monitoring study of ambient water (Kolpin et al., 2002). EPA has determined that this updated health data and additional occurrence data show that nonylphenol is anticipated to occur in PWSs, has potential adverse health effects and, therefore, merits listing on the Draft CCL 4.

EPA considered adding dicofol to the Draft CCL 4, however, both of the most recent manufacturers of the pesticide ceased all production as of May 17, 2011, and agreed to an EPA registration cancellation, which effectively prohibits all labeled uses of existing stocks after October 31, 2016. Use of dicofol has declined significantly in recent years. In addition, the chemical properties of dicofol indicate that it has low mobility in water because it is expected to adsorb to organic matter in soil and sediment and it has moderately low solubility in water. As a

result, the agency did not list dicofol on the Draft CCL 4 because it is not known or anticipated to occur in drinking water.

EPA evaluated the microbial contaminants nominated for the CCL 4 (see Exhibit 2) using the same process developed for the CCL 3. Taylor et al. (2001) was used as the basis of the microbial CCL 3 Universe, which includes a list of 1,415 known human pathogens. EPA added 10 additional microbes to the CCL 3 Universe based on CCL 3 public nominations and other available data, thus bringing the total number of microbes in the CCL 3 Universe to 1,425. More detailed information about the selection of the CCL 3 Universe for microbial contaminants can be found in the support document "Final Contaminant Candidate List 3 Microbes: Identifying the Universe" (USEPA, 2009b).

The microbes in the CCL 3 Universe were subsequently screened into the PCCL 3 by applying 12 criteria to narrow the CCL 3 Universe of all human pathogens to just those pathogens that could be transmitted through drinking water. More detailed information on the screening process developed under CCL 3 for the microbial contaminants can be found in the support document "Final Contaminant Candidate List 3 Microbes: Screening to the PCCL" (USEPA, 2009d).

All the microbes nominated for the CCL 4, with the exception of Heterotrophic Plate Count (HPC) bacteria, were already included in both the CCL 3 Universe and PCCL 3. Thus, the agency carried forward those microbes to the CCL 4 Universe and PCCL 4, respectively.

EPA reviewed new and/or updated sources of information for the nominated microbes on the PCCL 4 (i.e., Adenovirus, *Naegleria fowleri*, *Toxoplasma gondii* and *Vibrio cholerae*), and

determined that there were no new data that would change the scores or listing decisions for these contaminants.

Vibrio cholerae and *Toxoplasma gondii* will remain on the Draft PCCL 4 because there are no new data that would change the CCL 3 scores or listing decisions for these contaminants. *Naegleria fowleri* and Adenovirus were on the Final CCL 3 and are therefore being carried forward to the Draft CCL 4, along with the other microbes included on the Final CCL 3. A detailed description of the CCL 3 scoring protocol for microbes can be found in the support document "Final Contaminant Candidate List 3 Microbes: PCCL to CCL Process" (USEPA, 2009c). The data used to further evaluate the nominated microbes on the PCCL 4 can be found in the "Contaminant Information Sheets (CISs) for the Draft Fourth Preliminary Contaminant Candidate List (PCCL 4) Nominated Contaminants" (USEPA, 2015b).

The group of HPC bacteria was nominated for CCL 4, but EPA is not including it on the Draft CCL 4. HPC may include both pathogenic and harmless bacteria. However, available epidemiological evidence shows no relationship between gastrointestinal illness and HPC bacteria in drinking water (Calderon, 1988; Calderon and Mood, 1991; Payment et al., 1997; WHO, 2003). Thus, EPA considers the potential health risk of HPC bacteria in drinking water as likely negligible and is not including HPC on the Draft CCL 4. In addition, HPC bacteria are addressed by the treatment technique requirements under the Surface Water Treatment Rule, where they can be monitored in lieu of a disinfectant residual.

3. Evaluation of Previous Negative Regulatory Determinations

EPA evaluated the 20 contaminants from CCL 1 and CCL 2 for which the agency made negative regulatory determinations. EPA collected and evaluated new or updated data for the previous negative regulatory determinations, if data were available, from the data sources listed in section II.E.2(b), "Evaluation of Nominated Contaminants and Data Sources." Since regulatory determinations for the CCL 3 contaminants were recently made using the best available data, EPA did not include the CCL 3 regulatory determinations in this evaluation. EPA is adding manganese to the Draft CCL 4, as previously discussed in section 11.E.2, "Summary and Evaluation for CCL 4 Nominated Contaminants." The agency concluded there was not sufficient new information for any of the other 19 contaminants with previous negative regulatory determinations to justify including them on the Draft CCL 4. A listing of previous negative regulatory determinations is included in sections II.D.2 and II.D.4.

F. What is included on EPA's Draft CCL 4?

The Draft CCL 4 includes 100 chemicals and 12 microbes.

Exhibit 3. Draft Contaminant Candidate List 4:

Microbial Contaminants

Pathogens
Adenovirus
Caliciviruses
Campylobacter jejuni
Enterovirus
Escherichia coli (0157)
Helicobacter pylori

Hepatitis A virus
Legionella pneumophila
Mycobacterium avium
Naegleria fowleri
Salmonella enterica
Shigella sonnei

Chemical Contaminants[4]

Common Name – Registry Name	CASRN
1,1,1,2-Tetrachloroethane	630-20-6
1,1-Dichloroethane	75-34-3
1,2,3-Trichloropropane	96-18-4
1,3-Butadiene	106-99-0
1,4-Dioxane	123-91-1
17 alpha-Estradiol	57-91-0
1-Butanol	71-36-3
2-Methoxyethanol	109-86-4
2-Propen-1-ol	107-18-6
3-Hydroxycarbofuran	16655-82-6
4,4'-Methylenedianiline	101-77-9
Acephate	30560-19-1
Acetaldehyde	75-07-0
Acetamide	60-35-5
Acetochlor	34256-82-1
Acetochlor ethanesulfonic acid (ESA)	187022-11-3
Acetochlor oxanilic acid (OA)	194992-44-4
Acrolein	107-02-8

[4] Contaminants on the Final CCL 3 but not on the Draft CCL 4 are: 1, 3-dinitrobenzene, dimethoate, perchlorate, strontium, terbufos, and terbufos sulfone.

Common Name – Registry Name	CASRN
Alachlor ethanesulfonic acid (ESA)	142363-53-9
Alachlor oxanilic acid (OA)	171262-17-2
Alpha-Hexachlorocyclohexane	319-84-6
Aniline	62-53-3
Bensulide	741-58-2
Benzyl chloride	100-44-7
Butylated hydroxyanisole	25013-16-5
Captan	133-06-2
Chlorate	14866-68-3
Chloromethane (Methyl chloride)	74-87-3
Clethodim	110429-62-4
Cobalt	7440-48-4
Cumene hydroperoxide	80-15-9
Cyanotoxins	N/A
Dicrotophos	141-66-2
Dimethipin	55290-64-7
Disulfoton	298-04-4
Diuron	330-54-1
Equilenin	517-09-9
Equilin	474-86-2
Erythromycin	114-07-8
Estradiol (17-beta estradiol)	50-28-2
Estriol	50-27-1
Estrone	53-16-7
Ethinyl Estradiol (17-alpha Ethinyl Estradiol)	57-63-6
Ethoprop	13194-48-4
Ethylene glycol	107-21-1
Ethylene oxide	75-21-8
Ethylene thiourea	96-45-7
Fenamiphos	22224-92-6
Formaldehyde	50-00-0
Germanium	7440-56-4
Halon 1011 (bromochloromethane)	74-97-5
HCFC-22	75-45-6
Hexane	110-54-3

Common Name – Registry Name	CASRN
Hydrazine	302-01-2
Manganese	7439-96-5
Mestranol	72-33-3
Methamidophos	10265-92-6
Methanol	67-56-1
Methyl bromide (Bromomethane)	74-83-9
Methyl tertiary butyl ether (MTBE)	1634-04-4
Metolachlor	51218-45-2
Metolachlor ethanesulfonic acid (ESA)	171118-09-5
Metolachlor oxanilic acid (OA)	152019-73-3
Molinate	2212-67-1
Molybdenum	7439-98-7
Nitrobenzene	98-95-3
Nitroglycerin	55-63-0
N-Methyl-2-pyrrolidone	872-50-4
N-nitrosodiethylamine (NDEA)	55-18-5
N-nitrosodimethylamine (NDMA)	62-75-9
N-nitroso-di-n-propylamine (NDPA)	621-64-7
N-Nitrosodiphenylamine	86-30-6
N-nitrosopyrrolidine (NPYR)	930-55-2
Nonylphenol	25154-52-3
Norethindrone (19-Norethisterone)	68-22-4
n-Propylbenzene	103-65-1
o-Toluidine	95-53-4
Oxirane, methyl-	75-56-9
Oxydemeton-methyl	301-12-2
Oxyfluorfen	42874-03-3
Perfluorooctane sulfonic acid (PFOS)	1763-23-1
Perfluorooctanoic acid (PFOA)	335-67-1
Permethrin	52645-53-1
Profenofos	41198-08-7
Quinoline	91-22-5
RDX (Hexahydro-1,3,5-trinitro-1,3,5-triazine)	121-82-4
sec-Butylbenzene	135-98-8
Tebuconazole	107534-96-3

Common Name – Registry Name	CASRN
Tebufenozide	112410-23-8
Tellurium	13494-80-9
Thiodicarb	59669-26-0
Thiophanate-methyl	23564-05-8
Toluene diisocyanate	26471-62-5
Tribufos	78-48-8
Triethylamine	121-44-8
Triphenyltin hydroxide (TPTH)	76-87-9
Urethane	51-79-6
Vanadium	7440-62-2
Vinclozolin	50471-44-8
Ziram	137-30-4

III. Request for Comment

The purpose of this document is to present the Draft CCL 4 and seek comment on the contaminants selected for the Draft CCL 4, including any supporting data that can be used in developing the Final CCL 4. Data that the agency obtained and evaluated for developing the Draft CCL 4 may be found in the CCL 4 support documents located in the docket for this document. Specifically, the agency is asking for public comments on including manganese and nonylphenol on the CCL 4, and any additional data and information on manganese and nonylphenol health effects and concentrations in finished or ambient water. EPA is also seeking comment on ways the agency can improve or refine the selection process developed for CCL 3, and will take these comments into consideration when developing future CCLs. The agency will consider all information and comments received in determining the Final CCL 4, in the development of future CCLs, and in the EPA's efforts to set drinking water priorities in the future.

IV. EPA's Next Steps

Between now and the publication of the Final CCL 4, the agency will evaluate comments received during the public comment period for this document, consult with the EPA's Science Advisory Board and revise the CCL 4 as appropriate.

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